

## REMARKS

### Claim Amendments

Claims 1-34 are amended. New Claims 35-40 are added. The amendments to the claims and new claims are supported in the specification as-filed. By way of example and not limitation, the amendments to the claims and new claims are supported by the claims as-filed and at page 12, l. 35 to page 13, l. 17 and page 28, ll. 25-31. No new matter has been added. The claim amendments improve form and clarity and, except with respect to the claims that were not grouped, do not alter the grouping of the claims for purposes of the restriction requirement. Consideration and allowance of all claims are respectfully requested.

### Restriction Requirement

The Office Action requires election one of the following groups of claims for prosecution in connection with the present application:

- Group I**      claims 1, 2, 4-8, 12-18, drawn to a liquid pharmaceutical formulation comprising an Interleukin and capable of forming a gelled deposit *in vivo*;
- Group II**     claims 3-8, 12-15, 17, and 18, drawn to a liquid pharmaceutical formulation and capable of forming a gelled deposit *in vitro*;
- Group III**    claim 27, as drawn to claim 1, drawn to a method of making drugs for administration;
- Group IV**     claim 27, as drawn to claim 3, drawn to a method of making drugs for administration;
- Group V**      claims 28 and 29, as drawn to claim 1, drawn to a derived product comprising submicronic particles;
- Group VI**     claims 28 and 29, as drawn to claim 3, drawn to a derived product comprising submicronic particles;
- Group VII**    claims 30 and 31, as drawn to claim 1, drawn to a method of preparing a formulation with a colloidal suspension of nanoparticles;

- Group VIII** claims 30 and 31, as drawn to claim 3, drawn to a method of preparing a formulation with a colloidal suspension of nanoparticles;
- Group IX** claim 32, as drawn to claim 1, drawn to a method of preparing a formulation using a powder;
- Group X** claim 32, as drawn to claim 3, drawn to a method of preparing a formulation using a powder;
- Group XI** claim 33, as drawn to claim 1, drawn to a method of preparing a formulation by resuspending a powder produced by drying a liquid formulation;
- Group XII** claim 33, as drawn to claim 3, drawn to a method of preparing a formulation by resuspending a powder produced by drying a liquid formulation
- Group XIII** claim 34, as drawn to claim 1, drawn to a method of preparing a powder by drying a formulation; or
- Group XIV** claim 34, as drawn to claim 3, drawn to a method of preparing a powder by drying a formulation.

Election of Species Requirements

The Office Action requires election between the Formulae I, II, III, and IV.

Applicants' Elections of Group in Response to the Restriction Requirement

For purposes of complying with the election requirement, Applicants respectfully elect Group II, claims 3-8, 12-15, 17, and 18, with traverse. The Office Action noted that claims 9-11 and 19-26 could not be grouped. Applicants respectfully submit that claims 9-11 and 19-26, as amended, also fall within Group II and request their examination.

Applicants' Elections of Species

For purposes of complying with the election requirement, Applicants respectfully elect Formula I with traverse.

Applicants reserve the right to file a divisional application for any non-elected claims during the pendency of this application.

Applicants' elections are made without prejudice. As noted by the Examiner, upon the allowance of a generic claim, Applicants will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 C.F.R. 1.141.

#### Applicants' Traversal

With respect to Applicants' traversal, Applicants respectfully state:

Regarding the Restriction Requirement, the Office Action asserts that "The inventions listed as Groups I-XIV do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons: claim 1 lacks novelty as being anticipated by Huille et al., US Patent 5,904,936 (18 May 1999)." (Office Action at 3).

Regarding the Election of Species Requirement, the Office Action asserts that "These species are deemed to lack unity of invention because they are not so linked as to form a single general inventive concept under PCT Rule 13.1." (Office Action at 3).

Applicants respectfully submit that the reasons given by the Office Action for the species allegedly lacking the same or corresponding special technical features are improper. Applicants respectfully direct the Examiner's attention to Rule 13.2 of the Regulations Under the Patent Cooperation Treaty ("PCT Rules"), which states

Where a group of inventions is claimed in one and the same international application, the requirement of unity of invention referred to in Rule 13.1 shall be fulfilled only when there is a technical relationship among those inventions involving one or more of the same or corresponding special technical features. **The expression "special technical features" shall mean those technical features that define a contribution which each of the claimed inventions, considered as a whole, makes over the prior art.**

(Rule 13.2. *See also* MPEP § 1850, page 1800-96. (emphasis added)). Applicants also respectfully direct the Examiner's attention to page 1800-99 of the MPEP, which states

Unity of invention has to be considered in the first place only in relation to the independent claims in an international application and not the dependent claims.

\* \* \*

If the independent claims avoid the prior art and satisfy the requirement of unity of invention, no problem of lack of unity arises in respect of any claims that depend on the independent claims. In particular, it does not matter if a dependent claim itself contains a further invention.

(MPEP § 1850, page 1800-99).

Applicants respectfully submit that the independent claims of the application are patentable over the prior art.

A finding of Anticipation by a reference requires that the reference teach all limitations of the anticipated claims. Huille *et al.* fails to meet this requirement at least because it fails to teach formulations that form a gelled deposit in the presence of a protein, which is a feature that is shared by all claims. Accordingly, all of the claims do share a special technical feature and thus do possess unity of invention.

Applicants respectfully request withdrawal of the restriction and election of species requirements, and respectfully request consideration on the merits and allowance of all claims.

### **CONCLUSION**

Applicants respectfully request that this application be examined on the merits at the earliest possible time. Consideration and allowance of all claims are requested.

Should there be any outstanding matters that need to be resolved in the present application, the Examiner is respectfully requested to contact the undersigned below.

Applicants submit concurrently a request for a five month extension of time under 37 C.F.R. § 1.136 and the accompanying fee. Please charge our Credit Card in the amount of \$2,230.00 covering the fee set forth in 37 CFR § 1.136(a) and § 1.17(a). Please also charge our credit card \$300.00 for 6 extra dependent claims. Credit Card Payment Form SB-2038, with a signature from an authorized cardholder, is enclosed.

In the event that any additional extension of time is necessary to prevent the abandonment of this patent application, then such extension of time is petitioned. The U.S. Patent and Trademark Office is authorized to charge any additional fees that may be required in conjunction with this submission to our Deposit Account No. 50-2228, from which the undersigned is authorized to draw, under Order No. 022290.0158PTUS.

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Respectfully submitted,



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